

K901759 COBAS-FP REAGENTS FOR VANCOMYCINMay 2, 1990
14 days to decisionK901759 · Product code: **LEH** · Chemistry
Source: <https://www.510kdatabase.net/k901759/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Vancomycin (LEH)
Date received	Apr 18, 1990
Decision date	May 2, 1990
Days to decision	14 days
Third-party review	No
Combination product	No
PCCP authorized	No

APPLICANT

Company	Roche Diagnostic Systems, Inc.
Location	Mchenry, IL, US
Contact	ALEX WESOLOWSKI
510(k) history	296 submissions · 296 cleared · 1983-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k901759/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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